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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,304	09/24/2003	Bronislava Gedulin	18528.643 / 0101-UTL-0	8486
7590 08/20/2008 David Marsh 555 12th Street, N.W. Washington, DC 20004-1206			EXAMINER WINSTON, RANDALL O	
			ART UNIT 1655	PAPER NUMBER
			MAIL DATE 08/20/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/671,304	<b>Applicant(s)</b> GEDULIN ET AL.	
	<b>Examiner</b> Randall Winston	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,6,9,14-22 and 27-30 is/are pending in the application.
- 4a) Of the above claim(s) 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6,9,14-20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Acknowledgement is made of receipt and entry of the response amendment filed on 05/05/2008. Examiner acknowledges that claims 2-5, 10-13, have been cancelled and claims 21-22 are withdrawn. Examiner acknowledges that new claims 27-30 are added. Claims 1, 6, 9, 14-20 and new claims 27-30 will be examined on the merits.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 6, 9, 14-20 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Young et al. (US 5,677,279) in further view of Brain et al. (US 7045533) and Jorgensen et al. (US 4,370,317) and for the reasons set forth in the previous Office action which are restated below.

Applicant claims a method of treating pancreatitis and/or relieving the pain caused by pancreatitis in a mammalian subject (i.e. human) comprising administering to said subject an effective amount of the amylin analog of 25,28,29 Pro-h-amylin, a analgesic and a pancreatic enzyme.

Young teaches a method of relieving the pain and/or treating painful inflammation disorders in a mammalian subject comprising administering to said subject an effective amount of the same amylin analog as the claimed invention amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to treat painful inflammation disorders

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(see, e.g. see abstract, claims and claims 18-19 and column 4 lines 63-64). Young, however, does not teach that the mammalian subject's pain is caused by painful inflammation disorder such as pancreatitis nor Young teach the claimed pancreatic enzyme included within the composition.

Brain et al. beneficially teach that pancreatitis is a very painful inflammation condition and/or inflammation disorder (see, e.g. column 6 lines 7-14).

Jorgensen et al. beneficially teach that pancreatin treats pancreatitis (please note that pancreatin is defined as an extract from the pancreas of animals that contains pancreatic enzymes) (see, e.g. column 8 lines 36-41).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the same amylin analog as the claimed invention's amylin analog of 25,28,29 Pro-h-amylin and an analgesic to treat the painful inflammation disorder of pancreatitis in a mammalian subject because Young teaches that the amylin analog of 25,28,29 Pro-h-amylin and an analgesic treats painful inflammation disorders and Brain teaches that pancreatitis is a painful inflammation disorder. Thus, when the same amylin analog as the claimed invention's analog of 25,28,29 Pro-h-amylin in combination with an analgesic are administered to a mammalian subject for treating painful inflammation disorders, it would intrinsically treat the painful inflammation disorder of pancreatitis. Moreover, it would have been obvious to modify Young's administration's method of administering the same amylin analog as the claimed inventions amylin analog of 25,28,29 Pro-h-amylin in combination with an analgesic to include the teaching of Jorgensen which states a pancreatic enzyme such

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as pancreatin is well known in the art for treating pancreatitis because the above combined teachings would create an improved method of administering of treating the painful inflammation disorder of pancreatitis in a mammalian subject. The adjustments of other conventional working conditions (i.e. the substitution of the administration of one mammalian subject for another and determining suitable amounts/ranges of each active ingredient within the claimed composition), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Applicant arguments have been carefully considered but are not deemed persuasive. Applicant argues that Young describes the use of an amylin or amylin agonist for treating agonist for treating or preventing pain. Young does not teach or suggest the use of an amylin or an amylin agonist for treating pancreatitis. Moreover, Brain nor Jorgensen does not remedy Young's teachings because neither Brain nor Jorgensen describes treating the pain of pancreatitis. Neither Brain nor Jorgensen mentions or suggest the use of an amylin or an amylin agonist for use in treating pancreatitis. Therefore, alone or combined, the cited references do not teach or suggest that an amylin or an amylin analog can be used to treat pancreatitis.

However, for the reasons fully set forth above under USC 103, the above cited references of Young and Brain and Jorgensen, as a whole, reasonably suggest that the claimed amylin analog can be used to treat pancreatitis.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is (571)272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RW

/Christopher R. Tate/  
Primary Examiner, Art Unit 1655